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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/316,163

05/21/1999

WILHELM SCHWAEBLE

3523-P-002

7467

7590

07/23/2004

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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/316,163

Applicant(s)

SCHWAEBLE ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/22/04 AND 9/29/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5-8,11-19,22,23,26,30-32 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,17-19,22,23,26,30-32 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendments filed 3/22/04 and 9/29/03 are acknowledged and have been entered.

Claims 2, 17-19, 22, 23, 26, 30-32 and 36 are currently being examined.

The following are new grounds of rejection necessitated by Applicant's amendment filed 3/22/04.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 32 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 32 is indefinite in the recitation of "wherein said complement control protein modules consisting of 207 amino acids." because it is not clear what is meant.

b. Claim 36 is indefinite in the recitation of a "truncated recombinant factor H consisting of complement control protein modules 1-4 selected from the group consisting of complement control modules 1-6, 1-5 and 1-4 of complement factor H" because it is not clear what is meant.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 17-19, 22, 23, 26, 30-32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhn et al (Eur. J. Immunol. 1996, 26/10, 2383-2387) in view of Rimpoche et al (Applicant's IDS reference "A", previously provided) and admissions in the specification on page 15 at lines 4-5 and on page 2 at the last paragraph.

Kuhn et al teach that human factor H-like protein 1 (FHL-1) is composed of seven SCR that are identical in sequence to those of human factor H. Kuhn et al teach that DAF activity resides, i.e., essential and sufficient for activity, in the first four SCR, i.e. SCR 1-4 of both FHL-1 and factor H. Kuhn et al teach that factor H was more efficient in decay acceleration than factor FHL-1 in that about 100-fold less protein was required for a 50% inhibition of activity.

Kuhn et al does not teach a molecule consisting of complement control modules, i.e., SCR 1-4 of complement factor H.

Rimpoche et al teach full length and C-terminal truncated forms of factor H. Rimpoche et al teach factor H coupled to a chromatographic medium, i.e., an artificial membrane. Rimpoche et al teach testing of reactivity of antibodies with the immobilized factor H.

The admission in the specification on page 15 at lines 4-5 is that Seq ID NO: 9 is human factor H SCR 1-4. The admission in the specification on page 12 at the last paragraph is that FH_p43 is a human factor H glycoprotein.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a truncated mutant of FHL-1 that consists of the SCR 1-4 of FHL-1 (identical to SCR 1-4 of human factor H) taught by Kuhn et al and to have coupled it to a chromatographic medium as taught by Rimpoche et al.

One of ordinary skill in the art would have been motivated to do this in order to make a protein that could more efficiently effect decay acceleration at a lower concentration as taught by Kuhn et al and wherein coupling to an artificial membrane is effected, to test antibodies to SCR 1-4 as taught by Rimpoche et al for the full length and truncated forms of factor H taught by Rimpoche et al. With regard to instant claim 30, the recitation of a method wherein the claimed product is made, i.e., how it is coupled, carries no patentable weight in these product claims. With regard to instant claim 22 and dependent claims 23 and 32, the recitation of intended use in base claim 22 carries no patentable weight in these product claims.

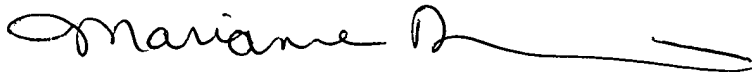
6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

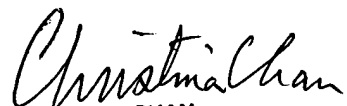
8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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July 21, 2004



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